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EXAMINER

NGUYEN, T

ART UNIT PAPER NUMBER

3308

DATE MAILED:

08/06/97

This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS

ARMSTRONG WESTERMAN HATTORI MCLELAND AND NAUGHTON 1725 K STREET NW SUITE 1000 WASHINGTON DC 20006

## **OFFICE ACTION SUMMARY**

| Responsive to communication(s) filed on   |   |
|---|---|
| This action is FINAL.   |   |
| Since this application is in condition for allowance except for formal matters; prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.   |   |
| A shortened statutory period for response to this action is set to expire (3) 4 whichever is longer, from the mailing date of this communication. Failure to respond the application to become abandoned. (35 U.S.C. § 133). Extensions of time may 1.136(a).               | d within the period for response will cause   |
| Disposition of Claims   |   |
| ✓ Claim(s)       1 - 9         Of the above, claim(s)          ✓ Claim(s)          ✓ Claim(s)          ☐ Claim(s)   | is/are withdrawn from consideration. is/are allowed. is/are rejected. is/are objected to. |
| Application Papers  |   |
| See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed on  |   |
| Priority under 35 U.S.C. § 119  |   |
| Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  All Some* None of the CERTIFIED copies of the priority documents have been received.  received in Application No. (Series Code/Serial Number)   |   |
| received in this national stage application from the International Bureau (PCT Rule 17.2(a)).   |   |
| *Certified copies not received:   |   |
| Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119   | (e).  |
| Attachment(s)   |   |
| Notice of Reference Cited, PTO-892  Information Disclosure Statement(s), PTO-1449, Paper No(s). 31/2  Interview Summary, PTO-413  Notice of Draftperson's Patent Drawing Review, PTO-948  Notice of Informal Patent Application, PTO-152  ■ SEF OFFICE ACTION ON THE FOLLOW | ING PAGES   |
| -SEE OFFICE ACTION ON THE FOLLOWING PAGES-  |   |

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**DETAILED ACTION** 

Claim Objections

1. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for

failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. The preamble of claim 4 differs from that of claims 1 to 3 upon

which it depends. Did applicant intend for claim 4 to be independent? If so, claim 4 is in

improper independent form. An independent claim cannot depend upon another claim.

Correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or

on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Zachariades

(U.S. Patent No. 4,655,769), for the following reason:

(1) With respect to claim 1, refer to Zachariades, col. 3, lines 52-61, which disclose an article

of ultra high molecular weight polyethylene (UHMWPE) having crystalline morphology, and thus

inherently, orientation of crystal planes.

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(2) With respect to claim 2, it is inherent that an article of ultra high molecular weight polyethylene (UHMWPE) having crystalline morphology would be crosslinked. Since applicant discloses on page 4, lines 8-16 and in the remarks (refer to the chart comparing applicant's invention to the invention of Rosenzweig, under step (b)), that crosslinking must occur first before the consequence of crystallinity can be obtained, the crystalline ultra high molecular weight polyethylene (UHMWPE) article of Zachariades meets this limitation.

- (3) With respect to claim 3, refer to col. 11, lines 11-12, wherein Zachariades discloses that the article of ultra high molecular weight polyethylene (UHMWPE) having crystalline morphology has a melting point in the range of 125°-270° C. Since applicant's range falls within his, Zachariades meets the limitation of this claim.
- (4) With respect to claim 4, refer to col. 1, lines 26-30, wherein Zachariades discloses that the article of ultra high molecular weight polyethylene (UHMWPE) having crystalline morphology can be shaped and used for use as orthopaedic prostheses.
- (5) With respect to claim 9, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. Zachariades meets all the limitations of this claim insofar as he discloses an article of ultra high molecular weight polyethylene (UHMWPE) having crystalline morphology, and thus inherently, orientation of crystal planes (refer to col. 3, lines 52-61).

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## Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zachariades '769 in view of Duan et al. (U.S. Patent No. 5,276,079), for the following reason:

With respect to claim 5, Zachariades discloses a method for producing an ultra high molecular weight polyethylene molded article having crystalline morphology by (1) crosslinking the ultra high molecular weight polyethylene molded article using chemical modifications, (2) heating the crosslinked article up to a deformable temperature, (3) compression-deforming the article, and (4) then cooling the article while keeping the article in a deformed state (refer to Zachariades, col. 5, lines 58-68 and col. 8, lines 34-39). However, Zachariades fails to disclose irradiating the article to introduce the crosslinking. Duan et al. teaches that crosslinking can be introduced by either using chemical crosslinking agents, or by irradiation, the latter being preferred for achieving slight crosslinking in articles which will be further compressed and molded (refer to Duan et al., col. 18, lines 50-68). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used irradiation to crosslink the article of Zachariades, as taught by Duan et al., in order to produce a slightly crosslinked article which could easily be compressed and molded, and since it is well known in the polymer art that addition of chemical agents and irradiation are alternative and analogous means for crosslinking.

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6. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zachariades '769 in view of Duan et al. '079, further in view of Rosenzweig (U.S. Patent No. 5,030,487), for the following reasons:

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- (1) With respect to claim 6, the modified Zachariades discloses the invention substantially as claimed, except for irradiation an ultra high molecular weight polyethylene article with a high energy radioactive ray having a dose of 0.01 to 5.0 Mrads. Rosenzweig teaches irradiating an ultra high molecular weight polyethylene article with a high energy radioactive ray having a dose of 0.01 to 5.0 Mrads, in order to achieve desirable heat shrinkability (refer to Rosenzweig, col. 14, lines 37-57). It would have been obvious to one of ordinary skill in the art at the time of the invention to have irradiated the ultra high molecular weight polyethylene article of Zachariades with a high energy radioactive ray having a dose of 0.01 to 5.0 Mrads, as taught by Rosenzweig, in order to achieve desirable heat shrinkability in this particular polymer.
- (2) With respect to claim 7, the modified Zachariades discloses that the melting point of the crystalline article is within the range of 125° 270° C, while the compression deformable temperature is 100° 170° C (refer to Zachariades, col. 4, lines 11-14 and col. 11, lines 11-15), and therefore meets the limitations of this claim.
- (3) With respect to claim 8, the modified Zachariades discloses that ultra high molecular weight polyethylene (UHMWPE) typically has a molecular weight of 2-8 million (refer to Zachariades, col. 2, lines 23-32). Therefore, it is obvious that the article of Zachariades before crosslinking had this molecular weight.

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Response to Arguments

7. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office 8. action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications regarding this application should be directed to Tram Nguyen at (703) 308-0804/(703)305-3590 (FAX). If you are unable to reach me, please contact my supervisor, John Weiss, at (703) 308-2702. In a case requiring immediate assistance, please call (703) 308-0858 to reach the main operator.

TAN August 1, 1997

DEBRA S. BRITTINGHAM PRIMARY EXAMINER

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